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09/808,512	03/14/2001	Kayode A. Williams	UOM 0193 PUS	4539

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EXAMINER

PATEL, MITAL B

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,512

Applicant(s)

WILLIAMS ET AL.

Examiner

Mital B. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-31 is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/29/03 has been entered.

Response to Amendment/Arguments

2. Applicant's arguments filed 4/29/03 have been fully considered but they are not persuasive.

3. In response to applicant's argument that the inlet opening is sized for connection to a standard breathing tube via an interference fit, the breathing tube remaining external to the body and that Clayton does not disclose or suggest delivery of gas via the medication tube, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as

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compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

4. Furthermore, in response to Applicant's arguments with respect to the FDA mandated sizes for a breathing tube, it should be noted that the breathing tube is not positively recited and the Examiner emphasis that the capability of the prior art being able to perform the intended use.

5. Applicant's also state that Clayton teaches that tube member 33 'can be made appropriate for micro-preemies, term infants, and pediatrics. It should be noted that Applicant's invention is geared to be used by pediatric patients, and therefore, Clayton clearly provides disclosure of tubing connection sized for a pediatric patient.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. There is a lack of antecedent basis for the following limitations:

- Claim 1, line 10, "the body"
- Claim 12, line 8, "the body"
- Claim 13, line 5, "the body"

Correction is required.

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9. As set forth by claims 1, 12, and 13, it is unclear as to what the Applicant means by the breathing tube and the inlet tube remaining external to the body since there is no prior recitation of the term "body."

10. As set forth by claims 1, 12, and 13, it is unclear as to what is meant by an interference fit.

Claim Rejections - 35 USC § 102

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. Claims 1-3, 6, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Clayton (US 6197044).

2. **As to claim 1**, Clayton teaches a medical pacifier for delivering gas to a patient, the pacifier comprising a nipple member **14** adapted to be received within an oral cavity of the patient, the nipple member having a conduit extending therethrough and an outlet opening **36** provided therein; and a base **16** attached to the nipple member and adapted to remain outside the oral cavity, the base including an inlet opening (see Figure 2) provided therein and a lumen **18** extending therethrough which is in fluid communication with the conduit of the nipple member, wherein the inlet opening is sized for connection to a standard breathing tube via an interference fit, the breathing tube remaining

external to the body such that gas can flow through the base and the nipple member for delivery via the outlet opening into the oral cavity of the patient.

3. **As to claim 2**, Clayton teaches a medical pacifier wherein the base includes a base plate disposed generally perpendicular to a longitudinal axis of the nipple member, the base plate having a concave front surface facing the nipple member and a convex rear surface facing away from the nipple member.

4. **As to claim 3**, Clayton teaches a medical pacifier wherein the base further includes a connector 33 projecting from the rear surface of the base plate, wherein the lumen extends through the connector and the inlet opening is disposed in a proximal end of the connector.

5. **As to claim 6**, Clayton teaches a medical pacifier wherein the outlet opening is provided in a distal end of the nipple member.

6. **As to claim 10**, Clayton teaches a medical pacifier wherein the pacifier is molded from a plastic material.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4, 5, 7, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clayton.

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9. **As to claim 4**, Clayton teaches essentially all of the limitations except for the specific dimensions of the connector. However, Applicant has not set forth how the particular limitation solves a stated problem or is advantages over the prior art, therefore, the connector of Clayton would perform equally as well. Finally, such a limitation may be arrived through routine observation and experimentation.

10. **As to claim 5**, Clayton teaches essentially all of the limitations except for the specific shape of the connector. However, Applicant has not set forth how the particular limitation solves a stated problem or is advantages over the prior art, therefore, the connector of Clayton would perform equally as well. Finally, such a limitation may be arrived through routine observation and experimentation.

11. **As to claim 7**, pacifiers with a handle ring pivotally attached to the rear surface of the base plate are known in the art (see cited references).

12. **As to claim 9**, pacifiers wherein the nipple member is impregnated with medication are known in the art (see cited references).

13. **As to claim 11**, Clayton teaches essentially all of the limitations except for wherein the pacifier is of one-piece construction. However, such a construction is known in the art (see cited references).

14. Claims 12-20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clayton in view of Despotis (US 4790327).

15. **As to claim 12**, Clayton teaches a medical pacifier for delivering gas to a patient, the pacifier comprising a base **16** adapted to remain outside an oral cavity of the patient, the base having a generally concave front surface and a generally convex rear

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surface, a connector **33** projecting from the base rear surface which includes an inlet opening provided in a proximal end thereof and a lumen **18** extending therethrough; a nipple member **14** projecting from the base front surface adapted to be received within an oral cavity of the patient, the nipple member having a conduit extending therethrough which is in fluid communication and an outlet opening **36** provided in a distal end therein, wherein the inlet opening is adapted to be connected to a source of anesthetic gas, such that anesthetic gas can flow through the pacifier for delivery via the outlet opening into the oral cavity of the patient. Clayton fails to specifically teach the proximal end of the connector having an outer diameter of approximately 15mm. However, Clayton does teach that the lumen receives a medication tube and it should be noted that a breathing tube constitutes a medication tube. Despotis, does teach a connector which specifically has an outer diameter of 15 mm for attaching a breathing tube. Therefore, it would have been obvious to one of ordinary skill in the art to make the connector of Clayton of a standard size, i.e., having a 15 mm outer diameter so that a standard breathing tube may be connected to the connector. Furthermore, connectors having the recited dimensions are well known in the art as cited by the prior art references.

16. **As to claim 13**, Clayton teaches an apparatus for inducing anesthesia in patient, the apparatus comprising a medical pacifier, the pacifier including a nipple member **14** adapted to be received within an oral cavity of the patient, the nipple member having a conduit extending therethrough and an outlet opening **36** provided therein, and a base **16** attached to the nipple member and adapted to remain outside the oral cavity, the

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base including an inlet opening provided therein and a lumen 18 extending therethrough which is in fluid communication with the conduit of the nipple member, wherein the inlet opening is adapted to be connected to the inlet tube such that anesthetic gas can flow through the base and the nipple member for delivery via the outlet opening into the oral cavity of the patient. Clayton fails to specifically teach a breathing circuit including a source of anesthetic gas and an inlet tube connected to the source and operable to transport the gas toward the patient. However, Clayton does disclose the use of the pacifier to administer medications through the tube. It would be well within the scope of one of ordinary skill to provide a breathing circuit with an inlet for delivering gases to the patient including a source of anesthetic gas as a form of administering medicament to the patient.

17. **As to claim 14**, Clayton teaches a medical pacifier wherein the base includes a base plate disposed generally perpendicular to a longitudinal axis of the nipple member, the base plate having a concave front surface facing the nipple member and a convex rear surface facing away from the nipple member.

18. **As to claim 15**, Clayton teaches a medical pacifier wherein the base further includes a connector 33 projecting from the rear surface of the base plate, wherein the lumen extends through the connector and the inlet opening is disposed in a proximal end of the connector.

19. **As to claim 16**, Clayton teaches essentially all of the limitations except for the specific dimensions of the connector. However, Applicant has not set forth how the particular limitation solves a stated problem or is advantages over the prior art, or

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provides an unexpected result. Therefore, the connector of Clayton would perform equally as well. Finally, such a limitation may be arrived through routine observation and experimentation.

20. **As to claim 17**, Clayton fails to specifically teach a breathing circuit which includes an outlet tube connected to the source, and the inlet tube and the outlet tube being joined to form a single tube end adapted to fitted over the proximal end of the connector. However, it would be well within the scope of one of ordinary skill in the art to provide an outlet tube to deliver gases from the patient and the limitation with respect to the outlet and inlet tube joined to form a single tube end may be arrived through routine observation and experimentation for ease of manageability of the breathing circuit.

21. **As to claim 18**, Clayton teaches essentially all of the limitations except for the specific shape of the connector. However, Applicant has not set forth how the particular limitation solves a stated problem or is advantages over the prior art, therefore, the connector of Clayton would perform equally as well. Finally, such a limitation may be arrived through routine observation and experimentation.

22. **As to claim 19**, Clayton teaches an apparatus wherein the outlet opening is provided in a distal end of the nipple member.

23. **As to claim 20**, pacifiers with a handle ring pivotally attached to the rear surface of the base plate are known in the art (see cited references).

24. **As to claim 22**, pacifiers wherein the nipple member is impregnated with medication are known in the art (see cited references).

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25. **As to claim 23**, Clayton teaches essentially all of the limitations except for wherein the pacifier is of one-piece construction. However, such a construction is known in the art (see cited references).

26. Claims 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clayton in view of Stevens (US 5810000).

27. **As to claim 8**, Clayton teaches essentially all of the limitations except for wherein the pacifier includes a longitudinal slit formed therein for receiving an endoscope. However, Stevens teaches a longitudinal slit formed in a pacifier to introduce an endotracheal tube for ventilating, anesthetizing, or supplying oxygen to infants. Therefore, it would be obvious to one of ordinary skill in the art to modify the pacifier of Clayton to include the longitudinal slit of Stevens to introduce an endotracheal tube for ventilating, anesthetizing, or supplying oxygen to infants.

28. Claims 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clayton in view of Despotis (US 4790327) further in view of Stevens (US 5810000).

29. **As to claim 21**, Clayton teaches essentially all of the limitations except for wherein the pacifier includes a longitudinal slit formed therein for receiving an endoscope. However, Stevens teaches a longitudinal slit formed in a pacifier to introduce an endotracheal tube for ventilating, anesthetizing, or supplying oxygen to infants. Therefore, it would be obvious to one of ordinary skill in the art to modify the pacifier of Clayton to include the longitudinal slit of Stevens to introduce an endotracheal tube for ventilating, anesthetizing, or supplying oxygen to infants.

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Allowable Subject Matter

30. Claims 24-31 are allowed over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mbp
May 31, 2003



**WEILUN LO
SUPERVISORY PATENT EXAMINER
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